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### Oríginal Review Article

## Digi Doctor- Concise Review of Telemedicine Practice Guidelines, 2020

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Article Info	Abstract
Received on: 04.05.2021 Accepted on: 28.06.2021 Key words Telemedicine Guidelines, Doctor- Patient Relationship, Tele-consultations, Confidentiality.	The healthcare industry has witnessed great advancements with the increasing use of technology. Telemedicine is one such advancement that has proved beneficial to ease the overburdened healthcare facilities. While telemedicine is a welcome change for doctors and other medical care providers, its impact on the doctor- patient relationship needs to be analysed in detail. Telemedicine Guidelines have laid down five categories of consultations according to the parties participating in these consultations. Provisions with respect to emergency consultations are summarily set out. The doctor-patient relationship is considered to be one of a contractual nature. In telemedicine as well, patient's consent to the consultation is essential. The guidelines duly recognise the technology cloak which surrounds telemedicine. A qualification is laid down to the effect that while it is the registered medical practitioner's responsibility to protect patient's data, the doctor shall not be responsible if there is a technology breach of data confidentiality. Laws governing medical practice need to be responsive to different facets of telemedicine. Test of reasonable man embodied in tort of medical negligence must be modified in light of impediments faced in a digital doctor-patient relationship. Therefore, while fixing liability on medical professionals, some qualifying factors need to be added.

#### 1. Introduction

The healthcare industry has witnessed great advancements with the increasing use of technology. Telemedicine is one such advancement that has proved beneficial to ease the overburdened healthcare facilities. While telemedicine is a welcome change for doctors and other medical care providers, its impact on the doctor- patient relationship needs to be analysed in detail.

Duties of medical practitioners set out by the Indian Medical Council (Professional conduct, Etiquette and Ethics) Regulations, 2002 like patient information confidentiality, maintenance of records etc. and aspects like patient's consent, guidelines regarding prescription are set to change with the use of technology.

#### 2. Indian Scenario

In India, practice of telemedicine has been tainted by the infamous case of **Deepa Sanjeev Pawaskar & Anr.v/s State of Maharashtra**<sup>1</sup> wherein it was held that it is a case of negligence of the doctor to prescribe through telemedicine. COVID-19 pandemic has practically changed the way of life and

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healthcare industry is no exception.

#### 2.1 Doctor's perspective:

Telemedicine consultations began to be widely adopted during the pandemic since, at times, it was difficult for patients to seek in-person consultations from their doctors. In order to provide clarity regarding use of telemedicine in the backdrop of the said judgement, the Board of Governors in supersession of the Medical Council of India published **'Telemedicine Practice Guidelines' on 25<sup>th</sup> March 2020.**<sup>2</sup>

The need to train medical professionals in the field of telemedicine is recognised at the very beginning of the guidelines. It is provided that a comprehensive program for imparting training in telemedicine needs to be designed. It shall be mandatory for all registered medical practitioners who intend to use telemedicine to complete an online course within three years of its notification. Surgical procedures and invasive procedures are excluded from the ambit of telemedicine.

According to the parties participating in consultations, five categories of consultations have been specified as follows:

- 1. Patient to Registered Medical Practitioner
- 2. Caregiver to Registered Medical Practitioner
- 3. Health Worker to Registered Medical Practitioner
- 4. Registered Medical Practitioner to Registered Medical Practitioner
- 5. Emergency Situations

Detailed procedure regarding the manner in which consultation is to be carried out in each of the five categories is described. Ordinarily, it is the patient who himself participates in the consultation. The guidelines also facilitate the caregiver supervising the patient to directly approach the medical practitioner. In such a scenario, the caregiver can be directly instructed about how to better support the patient. A third kind of consultation is also described where a health care worker like nurse, mid-level worker in the hospital etc. presently involved in patient's treatment can initiate the consultation. Since experience is of paramount importance in Medicine, using telemedicine, it is possible for one practitioner to approach another practitioner to deliberate and seek advice about a certain case.

The Guidelines lay down a full proof mechanism to prevent wrongs related to identity of both doctors and patients. Clause 3.2.1 mandates that telemedicine consultation should not be anonymous. Both patient and medical practitioners are required to provide their basic identity details. It is further provided by Clause 3.2.2 that it is upon the registered medical practitioner to ensure that there is a mechanism for a patient to verify the credentials and contact details of the doctor. Clause 3.2.4 casts a duty of informing the patients his name and qualifications while commencing the consultation upon the medical practitioner.

Indian Pursuant to Medical Council conduct, Etiquette Ethics) (Professional and Regulations, 2002, under Clause 3.2.5 of the guidelines it is required for the registered medical practitioner to display State Medical Council /Medical Council of India registration number on prescriptions, websites, electronic communication and receipts given to patients. There is flexibility about the mode of delivery of telemedicine. The consultation can be using video, audio or through text mode. The guidelines also provide for use of asynchronous modes like email, fax etc.<sup>3</sup> Although technology platforms used to conduct consultation may be different, uniform fundamental principles governing consultations are applicable. Video, audio and text modes make it possible to have real time dialogue between a medical practitioner and the patient or his caregiver, or between two or more medical practitioners. The asynchronous mode can be used for information exchange like biochemical and other diagnostic tests, radiological investigations' data etc.It is emphasized that medical practitioner should take into consideration patient's symptoms while deciding on the mode of consultation.<sup>3</sup>

The medical practitioner can advise the patient for a change of mode if it is necessary to analyse a particular symptom. The guidelines elucidate this aspect with the help of an illustration: there are be conditions where the registered medical practitioner will require hearing the patient speak and therefore, a voice interaction may be preferred to an email or text for a diagnosis. There are also situations where the registered medical practitioner needs to visually examine the patient and make a diagnosis. Detailed procedure regarding First Consultation and Follow-up Consultation is provided. First in-person consultation is always a preferred method as it enables the registered practitioner to comprehensively medical plan management. If first consultation is in itself a teleconsultation, then registered medical practitioner may have only a limited understanding of the patient seeking consultation. Principles governing emergency consultations are also laid down. It is emphasized that before planning treatment, new symptoms have to be examined. Therefore, even though critical and lifesaving steps can be suggested through telemedicine, the practitioner must advise in-person consultation. In emergency situations it is for the medical practitioner to use discretion and advise first aid, counselling or facilitate referral.

During in-person consultation, the patient walks in to a healthcare facility and experienced professionals make detailed observations about patient's ailment. This aspect of wholesome medical care is advanced in telemedicine guidelines too. After taking a holistic view of the situation, it is upon the registered medical practitioner to exercise their professional judgement to decide whether a telemedicine consultation is enough or an in-person consultation is required. Clause 3.7.4 lays down that it may be deemed to be misconduct of the registered medical practitioner to insist on telemedicine consultation when the patient is willing for an inperson consultation.

Certain clinical conditions require a thorough medical examination e.g.: a clue to arteritis will be absence of radial or ulnar pulse and this has to be done by palpating with three fingers. While a pulse oximeter can show the digital signal regarding rate and rhythm, force and tension are parameters which necessarily need the palpatory method. Hence, it is mandated, that registered medical practitioner should uphold the same standard of care as in personal consultation. The doctor-patient relationship is considered to be one of a contractual nature. The law of contract necessitates that for any contractual relationship to be established, free consent is of utmost importance. This requirement for in-person medical consultation is fulfilled by putting in practice the doctrine of Informed Consent. In telemedicine as well, patient's consent to the consultation is essential. The medical practitioner is cast upon a duty to take consent while initiating the consultation. Consent is said to be implied if consultation is initiated by the patient. However, if consultation is initiated by the registered medical practitioner, patient's consent has to be taken explicitly. Representative consent on behalf of minors is also recognised.<sup>4</sup>

It is the duty of medical practitioner to maintain records of previous consultations with the patient. The guidelines provide very broad ways to maintain records like maintaining call logs, emails etc. However, in the longer run, it is necessary to create a robust and tailor-made system for maintenance of digital documents relating to consultation. For telemedicine consultations it is necessary that the doctor is equipped with sufficient information of patient's medical condition. In a situation where additional investigations are required; medical practitioner can call for such investigations and pause the consultation for the time being.

Pursuant to the Indian Medical Council (Professional conduct, Etiquette and Ethics) Regulations, 2002, in telemedicine as well medical professionals are prohibited from advertising in any manner. The guidelines duly recognise the technology cloak which surrounds telemedicine. A qualification is laid down under clause 3.7.1.3 that while it is responsibility of registered medical practitioner to protect patient's data, the doctor shall not be responsible if there is a technology breach of data confidentiality

Medical practitioners are supposed to be accountable for consultation charges as well. Invoices need to be raised in the prescribed manner and complete details of all transactions are to be maintained. Telemedicine can also be used for health education relating to disease appropriate in the case; and/or provide counselling related to specific clinical condition; or prescribe medicines. Prescription of medicines is governed by **Drugs and Cosmetics Act,1940 and Narcotics and Psychotropic Substances Act,1985**.

**List O:** Medicines available 'over the counter' which can be used for any condition. These can be prescribed through all modes of telemedicine. E.g., paracetamol, ORS solutions, cough lozenges etc. Medicines that may be deemed necessary during public health emergencies.

**List A:** These medications are those which can be prescribed during the first consult which is a video consultation and are being re-prescribed for re-fill, in case of follow-up. This would be an inclusion list, containing relatively safe medicines with low potential for abuse.

**List B:** Is a list of medication which registered medical practitioner can prescribe in a patient who is undergoing follow-up consultation in addition to those which have been prescribed during in-person consult for the same medical condition.

**Prohibited List:** An RMP providing consultation cannot prescribe medicines in this list via telemedicine. These medicines have a high potential of abuse. Its improper

use may harm the patient and the society at large. Any Narcotic and Psychotropic substance listed in the **Narcotic Drugs and Psychotropic Substances, Act, 1985 and the medicines listed in Schedule X of Drug and Cosmetic Act and Rules.** It is permissible to issue and transmit E-prescriptions. If the medical practitioner directly transmits E-prescription to the pharmacy, patient's prior consent is mandatory for doing so.

#### 2.2 Patients' perspective:

Telemedicine is a step to guarantee access to medical assistance for patients in trying times of pandemics. As far as patients are concerned, the guidelines are indeed a visionary piece of legislation. The guidelines promote the right to medical care, a fundamental right recognised by Hon'ble Supreme Court in landmark case of **Pandit Parmanand Katara vs. Union of India**<sup>5</sup>, and at the same time duly recognise sensitive nature of patient's data.

The guidelines work in tandem with fundamental right of privacy guaranteed by the Indian Constitution. In order to make telemedicine sustainable and successful in the longer run, there is a need of comprehensive legislations like proposed Digital Information Security in Healthcare Act<sup>6</sup> thereby forming concrete laws to govern patient's data. Presently, Information Technology (Reasonable Security Practices and Procedures and Sensitive Personal Data or Information) Rules, 2011 classify only physical, psychological and mental health conditions, medical records and history as Sensitive personal data or information of a person.<sup>7</sup>

With increasing use of digital platforms for medical data transmission during pandemics, the Judiciary has ordered telemedicine companies to formulate guidelines regarding patient's data in the absence of which it is feared that a data epidemic will occur after the pandemic as was laid down by Kerala High Court in the case of **Balu Gopalakrishnan v. State of Kerala and Ors.**<sup>8</sup>

Part 5 of the guidelines lay down rules required to be followed by technology platforms facilitating telemedicine. One of the most important rules is that the technology platform has to verify name, qualification and registration number, contact details of every medical practitioner prior to listing on the platform. The purpose of these guidelines of facilitating doctor-patient interaction when in-person consultation is not possible is reiterated by prohibiting patient counselling and prescriptions directly by modalities of artificial intelligence. If the rules set out in part 5 are violated by the technology platform, the platform will be declared blacklisted and subsequent use shall be prohibited.

#### 3. Conclusion

It is submitted that through the guidelines a roadmap for implementation of telemedicine in the country is summarily put forth. However, laws governing medical practice need to be responsive to different facets of telemedicine. Test of reasonable man embodied in tort of medical negligence must be modified in light of impediments faced in a digital doctor-patient relationship. Therefore, while fixing liability on medical professionals, some qualifying factors need to be added.

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